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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,760	10/06/2006	Volker Doring	1022702-000304	5121
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EXAMINER				
LAU, JONATHAN S				
ART UNIT		PAPER NUMBER		
1623				
NOTIFICATION DATE		DELIVERY MODE		
12/09/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary

Application No.

10/560,760

Applicant(s)

DORING ET AL.

Examiner

Jonathan S. Lau

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-89 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 49-89 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/55/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

This Office Action details a Restriction Requirement and three Election of Species Requirements.

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Restriction Requirement

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 52-55 and 49-51 in part, drawn to a method for producing 2'-deoxynucleosides or 2'-deoxynucleoside precursors from a compound of formula (I) or its salts or a protected form thereof in a process comprising a decarboxylation step with

hydrogen peroxide to yield a compound of formula (II) or its salts or a protected form thereof as a 2'-deoxynucleoside precursor.

Group II, claim(s) 56-60 and 49-51 in part, drawn to a method for producing 2'-deoxynucleosides or 2'-deoxynucleoside precursors from a compound of formula (I) or its salts or a protected form thereof in a process comprising a decarboxylation step with an amine Y--H, wherein H represents a hydrogen atom bound to the nitrogen atom of the amino group, to produce a compound of formula (V), or its respective trans isomer or a protected form thereof, as a 2'-deoxynucleoside precursor.

Group III, claim(s) 61-63 and 49-51 in part, drawn to a method for producing 2'-deoxynucleosides or 2'-deoxynucleoside precursors from a compound of formula (I) or its salts or a protected form thereof in a process comprising a decarboxylation step.

Group IV, claim(s) 64-66 and 49-51 in part, drawn to a method for producing 2'-deoxynucleosides or 2'-deoxynucleoside precursors from a compound of formula (I) or its salts or a protected form thereof in a process comprising a decarboxylation step wherein the compound of formula (I) or its salts or a protected form thereof is converted to a compound of formula (VII), or its salts or a protected form thereof or a mixture of the respective epimers, which is then decarboxylated to yield a compound of formula (III) or a protected form thereof as a 2'-deoxynucleoside precursor.

Group V, claim(s) 68-82 and 49-51 in part, drawn to a method for producing 2'-deoxynucleosides or 2'-deoxynucleoside precursors from a compound of formula (I) or its salts or a protected form thereof in a process comprising a decarboxylation step

wherein the decarboxylation step is effected by an enzymatic reaction comprising a single step.

Group VI, claim(s) 83-85 and 49-51 in part, drawn to a method for producing 2'-deoxynucleosides or 2'-deoxynucleoside precursors from a compound of formula (I) or its salts or a protected form thereof in a process comprising a decarboxylation step comprising the preliminary step of producing the compound of formula (I) from D-gluconate or a D-gluconate salt by the use of a gluconate dehydratase activity.

Group VII, claim(s) 86-87 and 49-51 in part, drawn to a method for producing 2'-deoxynucleosides or 2'-deoxynucleoside precursors from a compound of formula (I) or its salts or a protected form thereof in a process comprising a decarboxylation step comprising the preliminary step of producing the compound of formula (I) from D-glucosamine by the use of a glucosamine deaminase activity.

Group VIII, claim(s) 88 and 89, drawn to an organism which is capable of enzymatically converting D-gluconate into 2-dehydro-3-deoxy-D-gluconate.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-VIII lack unity of invention because even though the inventions of these groups require the technical feature of a method for producing 2'-deoxynucleosides or 2'-deoxynucleoside precursors from a compound of formula (I) or its salts or a protected form thereof in a process comprising a decarboxylation step, this technical feature is not

a special technical feature as it does not make a contribution over the prior art in view of Fleche et al. (US Patent 5,872,247, issued 16 Feb 1999, cited in PTO-892) and De Ley (Naturwissenschaften, 1955, 42(4), p96, cited in PTO-892). Fleche et al. teaches catalytic decarboxylation of 2-ketoaldonic acids (column 1, lines 5-10) such as 2-keto-D-gluconic acid to give the ketose and aldose of the functionality immediately lower than the acid (column 1, lines 34-38) and teaches variation of the 2-ketoaldonic acid used (column 1, lines 5-15). De Ley teaches it is known in the prior art that 2-keto-3-deoxy-D-gluconate is closely related to 2-keto-D-gluconate (page 96, left column, paragraph 3). Therefore the method for producing 2'-deoxynucleoside precursors from a compound of formula (I) comprising a decarboxylation step is not inventive over the teachings of the prior art.

Election of Species Requirement

If Applicant elects the invention of **Group V**, Applicant is further required to elect from the following **First** Election of Species Requirement.

If Applicant elects the invention of **Group VI**, Applicant is further required to elect from the following **Second** Election of Species Requirement.

If Applicant elects the invention of **Group VII**, Applicant is further required to elect from the following **Third** Election of Species Requirement.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Examples of the species are as follows:

First species of TPP dependent keto acid decarboxylase:

- 1a) pyruvate decarboxylase (EC 4.1.1.1),
- 1b) benzoylformate decarboxylase (EC 4.1.1.7), and
- 1c) indolepyruvate decarboxylase (EC 4.1.1.74).

Second species of polynucleotide encoding the gluconate dehydratase:

2a) a nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID no 2,

2b) a nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID no 1,

2c) a nucleotide sequence encoding a fragment encoded by a nucleotide sequences encoding a polypeptide comprising the amino acid sequence of SEQ ID no 2, and

2d) nucleotide sequence hybridizing with a nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID no 2.

Third species of polynucleotide encoding the glucosaminatase deaminase:

3a) a nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID no 4,

3b) a nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID no 3,

2c) a nucleotide sequence encoding a fragment encoded by a nucleotide sequences encoding a polypeptide comprising the amino acid sequence of SEQ ID no 4, and

2d) nucleotide sequence hybridizing with a nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID no 4.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, all claims are generic.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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